

**Outcomes - CVD (Forms 121, 126, 132)****Data File:** ocvd\_ep\_fu\_pub**File Date:** 04/06/2006 **Structure:** One row per participant**Population:** E+P participants**Participant ID****Variable #** 1**Sas Name:** ID**Sas Label:** Participant ID**Usage Notes:** none**Categories:** Study: Administration**ECG pattern**

ECG pattern (Form 121)

**Variable #** 2**Sas Name:** ECGPATT**Sas Label:** ECG pattern**Usage Notes:** Associated with clinical MI**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
1	Evolving Q-wave and evolving ST-T abnormalities	65	0.4%
2	Equivocal Q-wave evol; evol ST-T abnormality; new left LBBB	59	0.4%
3	Q-waves or ST-T abnormalities suggestive of an MI	63	0.4%
8	Other ECG pattern, ECG uncodable, or normal ECG pattern	64	0.4%
9	ECG not available	20	0.1%
.	Missing	16,337	98.4%
		16,608	

**Centrally adjudicated clinical MI**

Centrally adjudicated clinical myocardial infarction (MI)

**Variable #** 3**Sas Name:** MI**Sas Label:** Central adj clinical MI**Usage Notes:** none**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,335	98.4%
1	Yes	273	1.6%
		16,608	

**Days from randomization to clinical MI**

Days from randomization to clinical myocardial infarction (MI)

**Variable #** 4**Sas Name:** MIDY**Sas Label:** Days from rand to clinical MI**Usage Notes:** none**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
273	1	2918	1075.2271	708.51929

**Central adj non-fatal MI including definite silent**

Centrally adjudicated non-fatal MI including definite silent MI

**Variable #** 5**Sas Name:** NOFATMI**Sas Label:** Central adj nonfatal MI including definite silent MI

Values		N	%
0	No	16,343	98.4%
1	Yes	265	1.6%
		16,608	

**Usage Notes:** Non-fatal defined as no definite coronary death occurring within 28 days of MI.**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Days from rand to non-fatal MI include def silent**

Days from randomization to non-fatal MI including definite silent MI

**Variable #** 6**Sas Name:** NOFATMIDY**Sas Label:** Days from rand to nonfatal MI including def silent MI

N	Min	Max	Mean	Std Dev
265	1	2918	1098.2226	720.28149

**Usage Notes:** Non-fatal defined as no definite coronary death occurring within 28 days of MI.**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Central adj non-fatal MI excluding definite silent**

Centrally adjudicated non-fatal MI excluding definite silent MI

**Variable #** 7**Sas Name:** NOFATMI2**Sas Label:** Central adj nonfatal MI excluding definite silent MI

Values		N	%
0	No	16,352	98.5%
1	Yes	256	1.5%
		16,608	

**Usage Notes:** Non-fatal defined as no definite coronary death occurring within 28 days of MI.**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Days from rand to non-fatal MI exclude def silent**

Days from randomization to non-fatal MI excluding definite silent MI

**Variable #** 8**Sas Name:** NOFATMI2DY**Sas Label:** Days from rand to nonfatal MI excluding def silent MI

N	Min	Max	Mean	Std Dev
256	1	2918	1076.3555	715.389

**Usage Notes:** Non-fatal defined as no definite coronary death occurring within 28 days of MI.**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

**Centrally adjudicated definite silent MI**

Variable # 9

Sas Name: DSMI

Sas Label: Central adj definite silent MI

Usage Notes: Determined by serial electrocardiography.

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,599	99.9%
1	Yes	9	0.1%
		16,608	

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**Days from randomization to definite silent MI**

Variable # 10

Sas Name: DSMIDY

Sas Label: Days from rand to definite silent MI

Usage Notes: Determined by serial electrocardiography.

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
9	1085	2302	1720.2222	597.49577

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**Centrally adjudicated possible silent MI**

Variable # 11

Sas Name: PSMI

Sas Label: Central adj possible silent MI

Usage Notes: Determined by serial electrocardiography.

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,550	99.7%
1	Yes	58	0.3%
		16,608	

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**Days from randomization to possible silent MI**

Variable # 12

Sas Name: PSMIDY

Sas Label: Days from rand to possible silent MI

Usage Notes: Determined by serial electrocardiography.

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
58	1075	2267	1485.1552	521.76316

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**Centrally adjudicated coronary death**

Centrally adjudicated coronary death (definite or possible coronary death)

Variable # 13

Sas Name: CORDTH

Sas Label: Central adj coronary death (definite or possible coronary death)

Usage Notes: none

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,535	99.6%
1	Yes	73	0.4%
		16,608	

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**Outcomes - CVD (Forms 121, 126, 132)****Data File:** ocvd\_ep\_fu\_pub**File Date:** 04/06/2006 **Structure:** One row per participant**Population:** E+P participants

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**Days from randomization to coronary death**

Days from randomization to coronary death (definite or possible coronary death)

**Variable #** 14**Usage Notes:** none**Sas Name:** CORDTHDY**Sas Label:** Days from rand to coronary death**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

	N	Min	Max	Mean	Std Dev
	73	9	2886	1215.6712	754.10099

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**CHD (clinical MI, def silent MI, coronary death)**

CHD (clinical MI, definite silent MI, or coronary death)

**Variable #** 15**Usage Notes:** none**Sas Name:** CHD**Sas Label:** CHD (clinical MI, definite silent MI, or coronary death)**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	16,273	98.0%
1	Yes	335	2.0%
		16,608	

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**Days from randomization to CHD**

Days from randomization to CHD (clinical MI, definite silent MI, or coronary death)

**Variable #** 16**Usage Notes:** none**Sas Name:** CHDDY**Sas Label:** Days from rand to CHD**Categories:** Medical History: Cardiovascular  
Outcome

	N	Min	Max	Mean	Std Dev
	335	1	2918	1117.1552	725.91156

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**Locally adjudicated hospitalized angina**

Locally adjudicated angina pectoris (including unstable angina) requiring and/or occurring during hospitalization

**Variable #** 17**Usage Notes:** Angina occurring on or after the same date as an MI was not counted since reporting of such events was not required by the study protocol.**Sas Name:** ANGINA**Sas Label:** Local adj hospitalized angina

Survival type analyses using angina as the endpoint should consider censoring the survival time at the date of MI if it occurred.

Values		N	%
0	No	16,241	97.8%
1	Yes	367	2.2%
		16,608	

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**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

**Days from randomization to hospitalized angina**

Days from randomization to angina pectoris (including unstable angina) requiring and/or occurring during hospitalization

**Variable #** 18

**Sas Name:** ANGINADY

**Sas Label:** Days from rand to hospitalized angina

	N	Min	Max	Mean	Std Dev
	367	12	2907	1102.5177	667.52341

**Usage Notes:** Angina occurring on or after the same date as an MI was not counted since reporting of such events was not required by the study protocol.

Survival type analyses using angina as the endpoint should consider censoring the survival time at the date of MI if it occurred.

**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

**Angina based on physician diagnosis and treatment**

Angina pectoris (including unstable angina) based on: Physician diagnosis of angina and receiving medical treatment at discharge, for angina on this admission (e.g. nitrate, beta-blocker, or calcium-channel blocker)

**Variable #** 19

**Sas Name:** ANGINADX1

**Sas Label:** Angina - phys dx & tx

**Usage Notes:** none

**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	41	0.2%
1	Yes	324	2.0%
.	Missing	16,243	97.8%
		16,608	

**Angina based on diagnosis, treatment, and revasc**

Angina pectoris (including unstable angina) based on: Physician diagnosis of angina and receiving medical treatment for angina on this admission plus current medical record documenting a history of coronary heart disease by previous catheterization or revascularization procedure.

**Variable #** 20

**Sas Name:** ANGINADX2

**Sas Label:** Angina - phys dx & tx + prior revasc

**Usage Notes:** none

**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	299	1.8%
1	Yes	66	0.4%
.	Missing	16,243	97.8%
		16,608	

**Angina based on CABG surgery or other revasc proc**

Angina pectoris (including unstable angina) based on: CABG surgery or other revascularization procedure on this admission

**Variable #** 21

**Sas Name:** ANGINADX3

**Sas Label:** Angina - current CABG/revasc

**Usage Notes:** none

**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	212	1.3%
1	Yes	153	0.9%
.	Missing	16,243	97.8%
		16,608	

**Angina based on 70%+ obstruction of coronary arter**

Angina pectoris (including unstable angina) based on: 70% or greater obstruction of any coronary artery on angiography on this admission

**Variable #** 22**Usage Notes:** none**Sas Name:** ANGINADX4**Categories:** Medical History: Cardiovascular  
Outcome**Sas Label:** Angina - current 70%+ obstruction

Values		N	%
0	No	193	1.2%
1	Yes	172	1.0%
.	Missing	16,243	97.8%
		16,608	

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**Angina based on ST effect by stress test with pain**

Angina pectoris (including unstable angina) based on: Horizontal or down-sloping ST-segment depression or abnormal ST elevation  $\geq 1$  mm on exercise or pharmacological stress testing with pain on this admission.

**Variable #** 23**Usage Notes:** none**Sas Name:** ANGINADX5**Categories:** Medical History: Cardiovascular  
Outcome**Sas Label:** Angina - ST dep/abn elev

Values		N	%
0	No	339	2.0%
1	Yes	26	0.2%
.	Missing	16,243	97.8%
		16,608	

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**Angina based on stress test positive for ischemia**

Angina pectoris (including unstable angina) based on: Scintigraphic or echocardiographic stress test positive for ischemia on this admission.

**Variable #** 24**Usage Notes:** none**Sas Name:** ANGINADX6**Categories:** Medical History: Cardiovascular  
Outcome**Sas Label:** Angina - scintigraphic/echocard +

Values		N	%
0	No	325	2.0%
1	Yes	40	0.2%
.	Missing	16,243	97.8%
		16,608	

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**Angina based on resting ECG ST effect with pain**

Angina pectoris (including unstable angina) based on: Resting ECG shows horizontal or down-sloping ST-segment depression or abnormal ST elevation  $\geq 1$  mm with pain that is not present on ECG without pain on this admission.

**Variable #** 25**Usage Notes:** none**Sas Name:** ANGINADX7**Categories:** Medical History: Cardiovascular  
Outcome**Sas Label:** Angina - resting ECG ST dep/abn elev

Values		N	%
0	No	353	2.1%
1	Yes	12	0.1%
.	Missing	16,243	97.8%
		16,608	

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**Locally adjudicated confirmed angina**

Locally adjudicated confirmed angina (stress test positive or obstructive coronary disease)

**Variable #** 26**Sas Name:** CONFANG**Sas Label:** Local adj confirmed angina (stress test + or obs coronary disease)

Values		N	%
0	No	16,376	98.6%
1	Yes	232	1.4%
		16,608	

**Usage Notes:** Angina occurring on or after the same date as an MI was not counted since reporting of such events was not required by the study protocol.

Survival type analyses using angina as the endpoint should consider censoring the survival time at the date of MI if it occurred.

**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Days from randomization to confirmed angina**

Days from randomization to confirmed angina (stress test positive or obstructive coronary disease)

**Variable #** 27**Sas Name:** CONFANGDY**Sas Label:** Days from rand to confirmed angina

N	Min	Max	Mean	Std Dev
232	12	2907	1143.7328	656.60827

**Usage Notes:** Angina occurring on or after the same date as an MI was not counted since reporting of such events was not required by the study protocol.

Survival type analyses using angina as the endpoint should consider censoring the survival time at the date of MI if it occurred.

**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Acute coronary syndrome (ACS)****Variable #** 28**Sas Name:** ACS**Sas Label:** Acute coronary syndrome (ACS)

Values		N	%
0	No	15,985	96.2%
1	Yes	621	3.7%
.	Missing	2	0.0%
		16,608	

**Usage Notes:** Defined as hospitalization for angina, Q-wave infarction or non-Q-wave infarction.**Categories:** Medical History: Cardiovascular  
Outcome**Days from randomization to acute coronary syndrome****Variable #** 29**Sas Name:** ACSDY**Sas Label:** Days from rand to ACS

N	Min	Max	Mean	Std Dev
621	1	2918	1089.3720	686.83257

**Usage Notes:** ACS is defined as hospitalization for angina, Q-wave infarction or non-Q-wave infarction.**Categories:** Medical History: Cardiovascular  
Outcome

**Acute coronary syndrome category**

Variable # 30

Sas Name: ACSCAT

Sas Label: Acute coronary syndrome (ACS) category

Usage Notes: ACS is defined as hospitalization for angina, Q-wave infarction or non-Q-wave infarction.

Categories: Medical History: Cardiovascular  
Outcome

Values		N	%
0	No ACS	15,985	96.2%
1	Unstable angina	367	2.2%
2	Non Q-wave MI	81	0.5%
3	Q-wave MI	173	1.0%
.	Missing	2	0.0%
		16,608	

**Locally adjudicated congestive heart failure**

Locally adjudicated congestive heart failure requiring and/or occurring during hospitalization. (Physician diagnosis of new-onset or worsened congestive heart failure on this admission).

Variable # 31

Sas Name: CHF

Sas Label: Local adj congestive heart failure

Usage Notes: none

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,386	98.7%
1	Yes	222	1.3%
		16,608	

**Days from randomization to congestive heart fail**

Days from randomization to congestive heart failure

Variable # 32

Sas Name: CHFDY

Sas Label: Days from rand to congestive heart failure

Usage Notes: none

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
222	7	2965	1200.6847	605.05588

**Locally adjudicated coronary revascularization**

Locally adjudicated coronary revascularization. Coronary artery bypass graft (CABG), percutaneous transluminal angioplasty (PTCA), coronary stent, or coronary atherectomy.

Variable # 33

Sas Name: REVASC

Sas Label: Local adj revascularization (CABG or PTCA)

Usage Notes: none

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,189	97.5%
1	Yes	419	2.5%
		16,608	



**Days from randomization to revascularization**

Days from randomization to coronary revascularization. Coronary artery bypass graft (CABG), percutaneous transluminal angioplasty (PTCA), coronary stent, or coronary atherectomy.

**Variable #** 34**Usage Notes:** none**Sas Name:** REVASCDY**Sas Label:** Days from rand to revascularization (CABG or PTCA)**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
419	3	2918	1136.0883	668.90041

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**Locally adjudicated carotid artery disease (CAD)**

Locally adjudicated carotid artery disease requiring and/or occurring during hospitalization. Disease must be symptomatic and/or requiring intervention (i.e. vascular or surgical procedure).

**Variable #** 35**Usage Notes:** CAD occurring on or after the same date as a stroke was not counted since reporting of such events was not required by the study protocol.**Sas Name:** CAD**Sas Label:** Local adj carotid artery disease (CAD)

Values	N	%
0 No	16,538	99.6%
1 Yes	70	0.4%
	16,608	

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Survival type analyses using CAD as the endpoint should consider censoring the survival time at the date of stroke if it occurred.

**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Days from randomization to carotid artery disease**

Days from randomization to carotid artery disease requiring and/or occurring during hospitalization. Disease must be symptomatic and/or requiring intervention (i.e. vascular or surgical procedure).

**Variable #** 36**Usage Notes:** CAD occurring on or after the same date as a stroke was not counted since reporting of such events was not required by the study protocol.**Sas Name:** CADDY**Sas Label:** Days from rand to CAD

N	Min	Max	Mean	Std Dev
70	16	2980	1076.5	846.49118

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Survival type analyses using CAD as the endpoint should consider censoring the survival time at the date of stroke if it occurred.

**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Carotid artery disease (CAD) diagnosis****Variable #** 37**Usage Notes:** none**Sas Name:** CADDIAG**Sas Label:** CAD diagnosis**Categories:** Medical History: Cardiovascular  
Outcome

Values	N	%
1 Carotid artery occlusion w/o document of cerebral infarction	67	0.4%
2 Carotid artery occlusion w/ document of cerebral infarction	2	0.0%
. Missing	16,539	99.6%
	16,608	

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**CAD based on hospital discharge summary**

Carotid artery disease based on: Symptomatic disease with carotid artery disease listed on the hospital discharge summary.

**Variable #** 38**Usage Notes:** none**Sas Name:** CADHSP**Sas Label:** CAD based on symp disease w/ CAD listed on hospital discharge summary**Categories:** Medical History: Cardiovascular Outcome

Values		N	%
0	No	0	0.0%
1	Yes	30	0.2%
.	Missing	16,578	99.8%
		16,608	

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**CAD based on carotid angiogram or doppler flow**

Carotid artery disease based on: Symptomatic disease with abnormal findings ( $\geq 50\%$  stenosis) on carotid angiogram or doppler flow study.

**Variable #** 39**Usage Notes:** none**Sas Name:** CADANGIO**Sas Label:** CAD based on symp disease w/ abnormal findings on carotid angiogram or doppler flow study**Categories:** Medical History: Cardiovascular Outcome

Values		N	%
0	No	0	0.0%
1	Yes	34	0.2%
.	Missing	16,574	99.8%
		16,608	

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**CAD based on vascular or surgical procedure**

Carotid artery disease based on: Vascular or surgical procedure to improve flow to the ipsilateral brain.

**Variable #** 40**Usage Notes:** none**Sas Name:** CADSURG**Sas Label:** CAD based on vascular or surgical procedure to improve flow to ipsilateral brain**Categories:** Medical History: Cardiovascular Outcome

Values		N	%
0	No	0	0.0%
1	Yes	56	0.3%
.	Missing	16,552	99.7%
		16,608	

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**Locally adjudicated HERS like CAD**

Locally adjudicated HERS like CAD with or without stroke and surgical or vascular procedure.

**Variable #** 41**Usage Notes:** none**Sas Name:** HERSCAD**Sas Label:** Local adj HERS like CAD (CAD w/ or w/o stroke & surg or vasc procedure)**Categories:** Medical History: Cardiovascular Outcome: Adjudicated

Values		N	%
0	No	16,552	99.7%
1	Yes	56	0.3%
		16,608	

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**Locally adj peripheral arterial disease (PAD)**

Locally adjudicated peripheral arterial disease (PAD) (aorta, iliac arteries, or below) requiring and/or occurring during hospitalization. Symptomatic disease including intermittent claudication, ischemic ulcers, or gangrene. Disease must be symptomatic and/or requiring intervention (e.g. vascular or surgical procedure for arterial insufficiency in the lower extremities or abdominal aortic aneurysm).

**Variable #** 42**Usage Notes:** none**Sas Name:** PAD**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Sas Label:** Local adj peripheral arterial disease (PAD)

Values		N	%
0	No	16,539	99.6%
1	Yes	69	0.4%
		16,608	

**Days from randomization to PAD**

Days from randomization to peripheral arterial disease (PAD)

**Variable #** 43**Usage Notes:** none**Sas Name:** PADDY**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Sas Label:** Days from rand to PAD

	N	Min	Max	Mean	Std Dev
	69	30	2710	1177.0580	687.5417

**Peripheral arterial disease (PAD) diagnosis****Variable #** 44**Usage Notes:** none**Sas Name:** PADDIAG**Categories:** Medical History: Cardiovascular  
Outcome**Sas Label:** PAD diagnosis

Values		N	%
1	Lower extremity claudication	20	0.1%
2	Atherosclerosis of arteries of the lower extremities	27	0.2%
3	Arterial embolism and/or thrombosis of the lower extremities	7	0.0%
4	Abdominal aortic aneurysm (AAA)	14	0.1%
.	Missing	16,540	99.6%
		16,608	

**Locally adjudicated lower extremity disease**

Locally adjudicated lower extremity disease (claudication, atherosclerosis of arteries, or arterial embolism and/or thrombosis of lower extremities)

**Variable #** 45**Usage Notes:** none**Sas Name:** LOEXTREM**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated**Sas Label:** Local adj lower extremity disease (claudication, atherosclerosis of arteries, or arterial embolism &/or thrombosis of lower extremities)

Values		N	%
0		16,556	99.7%
1		52	0.3%
		16,608	

**Locally adjudicated abdominal aortic aneurysm**

Locally adjudicated abdominal aortic aneurysm (with or without surgical or vascular procedure).

Variable # 46

Usage Notes: none

Sas Name: AAA

Sas Label: Local adj abdominal aortic aneurysm (AAA w/ or w/o surg or vasc procedure)

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,591	99.9%
1	Yes	17	0.1%
		16,608	

**Locally adj HERS like lower extremity disease**

Locally adjudicated HERS like lower extremity disease

Variable # 47

Usage Notes: none

Sas Name: HERSLOEX

Sas Label: Local adj HERS like lower extremity disease

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,568	99.8%
1	Yes	40	0.2%
		16,608	

**Locally adjudicated total CAD and/or PAD**

Locally adjudicated total peripheral arterial disease (CAD and/or PAD)

Variable # 48

Usage Notes: none

Sas Name: PVD

Sas Label: Local adj total peripheral arterial disease (CAD + PAD)

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,477	99.2%
1	Yes	131	0.8%
		16,608	

**Days from randomization to total CAD and/or PAD**

Days from randomization to total peripheral arterial disease (CAD and/or PAD)

Variable # 49

Usage Notes: none

Sas Name: PVDDY

Sas Label: Days from rand to total CAD+PAD

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
131	16	2980	1118.3817	758.97273

**Centrally adjudicated deep vein thrombosis (DVT)**

Variable # 50

Usage Notes: none

Sas Name: DVT

Sas Label: Central adj deep vein thrombosis (DVT)

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,426	98.9%
1	Yes	182	1.1%
		16,608	

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**Days from randomization to DVT**

Variable # 51

Usage Notes: none

Sas Name: DVTDY

Sas Label: Days from rand to DVT

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
182	22	2749	1021.5	695.81473

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**Centrally adjudicated idiopathic DVT**

Centrally adjudicated deep vein thrombosis of lower extremities not resulting from a procedure within 60 days.

Variable # 52

Usage Notes: none

Sas Name: DVT1

Sas Label: Central adj idiopathic DVT

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,465	99.1%
1	Yes	127	0.8%
.	Missing	16	0.1%
		16,608	

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**Days from randomization to idiopathic DVT**

Days from randomization to deep vein thrombosis of lower extremities not resulting from a procedure within 60 days.

Variable # 53

Usage Notes: none

Sas Name: DVT1DY

Sas Label: Days from rand to idiopathic DVT

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
127	22	2528	1048.4331	676.47145

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**Centrally adjudicated secondary DVT**

Centrally adjudicated deep vein thrombosis of lower extremities during or following a procedure within 60 days.

**Variable #** 54**Usage Notes:** none**Sas Name:** DVT2**Sas Label:** Central adj secondary DVT**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,553	99.7%
1	Yes	39	0.2%
.	Missing	16	0.1%
		16,608	

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**Days from randomization to secondary DVT**

Days from randomization to deep vein thrombosis of lower extremities during or following a procedure within 60 days.

**Variable #** 55**Usage Notes:** none**Sas Name:** DVT2DY**Sas Label:** Days from rand to secondary DVT**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
39	67	2749	1210.2051	732.0961

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**DVT based on hospital discharge summary**

Diagnosis of deep vein thrombosis is based on: Hospital discharge summary with a diagnosis of deep vein thrombosis.

**Variable #** 56**Usage Notes:** none**Sas Name:** DVTDSCHG**Sas Label:** DVT based on hospital discharge summary**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	0	0.0%
1	Yes	154	0.9%
.	Missing	16,454	99.1%
		16,608	

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**DVT based on postive findings on a venogram**

Diagnosis of deep vein thrombosis is based on: Positive findings on a venogram.

**Variable #** 57**Usage Notes:** none**Sas Name:** DVTVENO**Sas Label:** DVT based on postive venogram**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	0	0.0%
1	Yes	13	0.1%
.	Missing	16,595	99.9%
		16,608	

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**DVT based on positive impedance plethysmography**

Diagnosis of deep vein thrombosis is based on: Positive findings using impedance plethysmography.

**Variable #** 58**Usage Notes:** none**Sas Name:** DVTIMPED**Sas Label:** DVT based on impedance plethysmography**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	0	0.0%
1	Yes	3	0.0%
.	Missing	16,605	100.0%
		16,608	

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**DVT based on positive finding on non-invasive exam**

Diagnosis of deep vein thrombosis is based on: Positive findings on doppler duplex, ultrasound, sonogram, or other non-invasive test examination.

**Variable #** 59**Usage Notes:** none**Sas Name:** DVTNOINV**Sas Label:** DVT based on non-invasive exam**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	0	0.0%
1	Yes	144	0.9%
.	Missing	16,464	99.1%
		16,608	

---

**DVT based on positive findings on isotope scan**

Diagnosis of deep vein thrombosis is based on: Positive findings on isotope scan.

**Variable #** 60**Usage Notes:** none**Sas Name:** DVTISOTOP**Sas Label:** DVT based on isotope scan**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	0	0.0%
1	Yes	0	0.0%
.	Missing	16,608	100.0%
		16,608	

---

**Diagnosis of DVT reporting source**

Variable # 61

Sas Name: DVTREPT

Sas Label: DVT diagnosis reporting source

Usage Notes: none

Categories: Medical History: Cardiovascular  
Outcome

Values		N	%
1	Hospital inpatient	90	0.5%
2	Hospital outpatient facility or clinic	4	0.0%
3	Radiology or imaging facility	7	0.0%
4	Physician's office/private medical practitioner	1	0.0%
5	Nursing/convalescent home/hospice	0	0.0%
6	Autopsy only	1	0.0%
7	Death certificate only	0	0.0%
8	Other	0	0.0%
.	Missing	16,505	99.4%
		16,608	

---

**Work up for pulmonary embolism (PE) performed**

Variable # 62

Sas Name: PEWORKUP

Sas Label: Work- up for PE performed

Usage Notes: none

Categories: Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	79	0.5%
1	Yes	69	0.4%
8	Unknown	18	0.1%
.	Missing	16,442	99.0%
		16,608	

---

**Centrally adjudicated pulmonary embolism (PE)**

Centrally adjudicated pulmonary embolism (PE) requiring hospitalization.

Variable # 63

Sas Name: PE

Sas Label: Central adj pulmonary embolism (PE)

Usage Notes: none

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,484	99.3%
1	Yes	124	0.7%
		16,608	

---

**Days from randomization to pulmonary embolism (PE)**

Variable # 64

Sas Name: PEDY

Sas Label: Days from rand to PE

Usage Notes: none

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
124	21	2744	1129.0887	742.10395

---



**Centrally adjudicated idiopathic PE**

Centrally adjudicated pulmonary embolism (PE) not resulting from a procedure within 60 days.

**Variable #** 65**Usage Notes:** none**Sas Name:** PE1**Sas Label:** Central adj idiopathic PE**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,512	99.4%
1	Yes	88	0.5%
.	Missing	8	0.0%
		16,608	

---

**Days from randomization to idiopathic PE**

Days from randomization to pulmonary embolism (PE) not resulting from a procedure within 60 days.

**Variable #** 66**Usage Notes:** none**Sas Name:** PE1DY**Sas Label:** Days from rand to idiopathic PE**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
88	25	2509	1144.7386	725.57173

---

**Centrally adjudicated secondary PE**

Centrally adjudicated pulmonary embolism (PE) during or following a procedure within 60 days

**Variable #** 67**Usage Notes:** none**Sas Name:** PE2**Sas Label:** Central adj secondary PE**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0		16,572	99.8%
1		28	0.2%
.	Missing	8	0.0%
		16,608	

---

**Days from randomization to secondary PE**

Days from randomization to pulmonary embolism (PE) during or following a procedure within 60 days

**Variable #** 68**Usage Notes:** none**Sas Name:** PE2DY**Sas Label:** Days from rand to secondary PE**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
28	67	2744	1261.75	777.21495

---

**PE based on hospital discharge summary**

Diagnosis of pulmonary embolism is based on: Hospital discharge summary with a diagnosis of pulmonary embolism.

**Variable #** 69**Usage Notes:** none**Sas Name:** PEDSCHG**Categories:** Medical History: Cardiovascular Outcome**Sas Label:** PE based on hospital discharge summary

Values		N	%
0	No	0	0.0%
1	Yes	111	0.7%
.	Missing	16,497	99.3%
		16,608	

---

**PE based on ventilation-perfusion lung scan**

Diagnosis of pulmonary embolism is based on: High probability on ventilation-perfusion lung scan (exclude moderate, intermediate, or low probability on ventilation-perfusion lung scan).

**Variable #** 70**Usage Notes:** none**Sas Name:** PELNGSCAN**Categories:** Medical History: Cardiovascular Outcome**Sas Label:** PE based on ventilation-perfusion lung scan

Values		N	%
0	No	0	0.0%
1	Yes	74	0.4%
.	Missing	16,534	99.6%
		16,608	

---

**PE based on pulmonary angiogram or spiral CT**

Diagnosis of pulmonary embolism is based on: Positive findings on pulmonary angiogram or spiral CT.

**Variable #** 71**Usage Notes:** none**Sas Name:** PEANGIO**Categories:** Medical History: Cardiovascular Outcome**Sas Label:** PE based on pulmonary angiogram

Values		N	%
0	No	0	0.0%
1	Yes	33	0.2%
.	Missing	16,575	99.8%
		16,608	

---

**PE based on DVT and signs suggestive of PE**

Diagnosis of pulmonary embolism is based on: Diagnosis of deep vein thrombosis (DVT) based on  $\geq 1$  DVT criteria, plus signs and symptoms suggestive of PE (e.g., acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest x-ray findings suggestive of PE).

**Variable #** 72**Usage Notes:** none**Sas Name:** PESUGGEST**Categories:** Medical History: Cardiovascular Outcome**Sas Label:** PE based on suggestive signs & DVT

Values		N	%
0	No	0	0.0%
1	Yes	33	0.2%
.	Missing	16,575	99.8%
		16,608	

---

**PE based on other, including autopsy**

Diagnosis of pulmonary embolism is based on: Other, including autopsy.

**Variable #** 73**Usage Notes:** none**Sas Name:** PEOTHER**Sas Label:** PE based on other, including autopsy**Categories:** Medical History: Cardiovascular  
Outcome

Values		N	%
0	No	0	0.0%
1	Yes	2	0.0%
.	Missing	16,606	100.0%
		16,608	

---

**Centrally adjudicated venousthromboembolism**

Centrally adjudicated venousthromboembolism (VT: DVT and/or PE).

**Variable #** 74**Usage Notes:** none**Sas Name:** VTE**Sas Label:** Central adj venousthromboembolism (VT: PE &/or DVT)**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,365	98.5%
1	Yes	243	1.5%
		16,608	

---

**Days from randomization to VT**

Days from randomization to venousthromboembolism (VT: DVT and/or PE).

**Variable #** 75**Usage Notes:** none**Sas Name:** VTEDY**Sas Label:** Days from rand to VT**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

	N	Min	Max	Mean	Std Dev
	243	21	2744	1036.4156	701.97861

---

**Centrally adjudicated idiopathic VT**

Centrally adjudicated VT not resulting from a procedure within 60 days.

**Variable #** 76**Usage Notes:** none**Sas Name:** VTE1**Sas Label:** Central adj idiopathic VT**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,415	98.8%
1	Yes	171	1.0%
.	Missing	22	0.1%
		16,608	

---

**Days from randomization to idiopathic VT**

Days from randomization to VT not resulting from a procedure within 60 days.

**Variable #** 77**Usage Notes:** none**Sas Name:** VTE1DY**Sas Label:** Days from rand to idiopathic VT**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

	N	Min	Max	Mean	Std Dev
	171	22	2528	1068.8947	690.73456

---

**Centrally adjudicated secondary VT**

Centrally adjudicated VT during or following a procedure within 60 days

**Variable #** 78**Usage Notes:** none**Sas Name:** VTE2**Sas Label:** Central adj secondary VT**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,536	99.6%
1	Yes	50	0.3%
.	Missing	22	0.1%
		16,608	

---

**Days from randomization to secondary VT**

Days from randomization to VT during or following a procedure within 60 days

**Variable #** 79**Usage Notes:** none**Sas Name:** VTE2DY**Sas Label:** Days from rand to secondary VT**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

	N	Min	Max	Mean	Std Dev
	50	67	2744	1198.82	719.84215

---

**Centrally adjudicated stroke**

Centrally adjudicated stroke requiring and/or occurring during hospitalization: Rapid onset of a persistent neurologic deficit attributable to an obstruction or rupture of the arterial system (including stroke occurring during or resulting from a procedure)\*. Deficit is not known to be secondary to brain trauma, tumor, infection, or other cause. Deficit must last more than 24 hours, unless death supervenes or there is a demonstrable lesion compatible with acute stroke on CT or MRI scan.

\*A stroke is defined as procedure-related if it occurs within 24 hours after any procedure or within 30 days after a cardioversion or invasive cardiovascular procedure

**Variable #** 80**Usage Notes:** none**Sas Name:** STROKE**Sas Label:** Central adj stroke**Categories:** Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	16,350	98.4%
1	Yes	258	1.6%
		16,608	

---



Days from randomization to stroke

Variable # 81  
Sas Name: STROKEDY  
Sas Label: Days from rand to stroke

Usage Notes: none  
Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
258	6	2744	1190.1434	673.383

Stroke diagnosis

Variable # 82  
Sas Name: DIAGNOSIS  
Sas Label: Stroke diagnosis

Usage Notes: none  
Categories: Medical History: Cardiovascular  
Outcome

Values	N	%
0 No stroke	16,350	98.4%
1 Subarachnoid hemorrhage	10	0.1%
2 Intraparenchymal hemorrhage	27	0.2%
3 Other or unspecified intracranial hemorrhage (nontraumatic)	1	0.0%
4 Occlusion of cerebral or pre-cerebral arteries with infarct	206	1.2%
5 Acute, but ill-defined, cerebrovascular disease	2	0.0%
6 Central-nervous system complications	1	0.0%
7 Report of cerebrovascular death only	11	0.1%
	16,608	

Oxfordshire classification

Variable # 83  
Sas Name: OXFORD  
Sas Label: Oxfordshire classification

Usage Notes: none  
Categories: Medical History: Cardiovascular  
Outcome

Values	N	%
1 Total anterior circulation infarct (TACI)	12	0.1%
2 Partial anterior circulation infarct (PACI)	85	0.5%
3 Lacunar infarction (LACI)	76	0.5%
4 Posterior circulation infarct (POCI)	33	0.2%
- Missing	16,402	98.8%
	16,608	

**TOAST classification**

Trial of Org 10172 in Acute Stroke Treatment (TOAST) Classification

Variable # 84

Usage Notes: none

Sas Name: TOAST

Sas Label: Toast classification

Categories: Medical History: Cardiovascular  
Outcome

Values		N	%
1	Probable large artery atherosclerosis (embolus/thrombosis)	22	0.1%
2	Probable cardioembolism (high-risk/medium risk)	21	0.1%
3	Probable small vessel occlusion (lacune)	41	0.2%
4	Probable stroke of other determined etiology	10	0.1%
5	Possible large artery atherosclerosis (embolus/thrombosis)	6	0.0%
6	Possible cardioembolism (high-risk/medium risk)	3	0.0%
7	Possible small vessel occlusion (lacune)	17	0.1%
10	Possible stroke of other determined etiology	5	0.0%
11	Stroke of undetermined etiology: 2 or more causes identified	2	0.0%
12	Stroke of undetermined etiology: Negative evaluation	34	0.2%
13	Stroke of undetermined etiology: Incomplete evaluation	45	0.3%
.	Missing	16,402	98.8%
		16,608	

---

**Glasgow outcome scale**

Participant's functional status at the time of hospital discharge for stroke (Glasgow Outcome Scale)

Variable # 85

Usage Notes: none

Sas Name: GLASGOW

Sas Label: Glasgow outcome scale

Categories: Medical History: Cardiovascular  
Outcome

Values		N	%
1	Good recovery	80	0.5%
2	Moderately disabled	78	0.5%
3	Severely disabled	53	0.3%
4	Vegetative survival	5	0.0%
5	Dead	23	0.1%
6	Unable to categorize stroke	18	0.1%
.	Missing	16,351	98.5%
		16,608	

---



Outcomes - CVD (Forms 121, 126, 132)

Data File: ocvd\_ep\_fu\_pub      File Date: 04/06/2006      Structure: One row per participant      Population: E+P participants

MI, coronary death, PTCA, CABG, or angina

Variable # 86

Usage Notes: none

Sas Name: TOTCHD

Sas Label: MI, coronary death, PTCA, CABG, or angina

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

Values		N	%
0	No	15,883	95.6%
1	Yes	725	4.4%
		16,608	

Days from rand to MI, cor. death, PTCA, CABG, ang

Days from randomization to first occurrence of MI, coronary death, PTCA, CABG, or angina

Variable # 87

Usage Notes: none

Sas Name: TOTCHDDY

Sas Label: Days from rand to MI, coronary death, PTCA, CABG, or angina

Categories: Medical History: Cardiovascular  
Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
725	1	2918	1109.7476	688.12045